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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,441	05/10/2000	LASZLO BALAZS	1060-136P	1924

2292 7590 03/26/2003
BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 03/26/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/485,441	Applicant(s) BALAZS et al.	
	Examiner Brenda Coleman	Art Unit 1624	
	-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --		
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.			
- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).			
Status			
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Jan 10, 2003</u>			
2a) <input checked="" type="checkbox"/> This action is FINAL. 2b) <input type="checkbox"/> This action is non-final.			
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.			
Disposition of Claims			
4) <input checked="" type="checkbox"/> Claim(s) <u>1-14 and 16-18</u> is/are pending in the application.			
4a) Of the above, claim(s) _____ is/are withdrawn from consideration.			
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.			
6) <input checked="" type="checkbox"/> Claim(s) <u>1-14 and 16-18</u> is/are rejected.			
7) <input type="checkbox"/> Claim(s) _____ is/are objected to.			
8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.			
Application Papers			
9) <input type="checkbox"/> The specification is objected to by the Examiner.			
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.			
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.			
Priority under 35 U.S.C. §§ 119 and 120			
13) <input checked="" type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).			
a) <input checked="" type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. <input checked="" type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received.			
14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.			
15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.			
Attachment(s)			
1) <input type="checkbox"/> Notice of References Cited (PTO-892)		4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____	
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)	
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____		6) <input type="checkbox"/> Other: _____	

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DETAILED ACTION

Claims 1-14 and 16-18 are pending in the application.

This action is in response to applicant's amendments dated January 10, 2003. Claims 1, 8, 9, 16 and 17 have been amended and claim 18 is newly added.

Response to Arguments

Applicant's arguments filed January 10, 2003 have been fully considered with the following effect:

1. The applicant's amendments are sufficient to overcome the 35 USC § 112, second paragraph rejection of the last office action which is hereby **withdrawn**.
2. The applicant's amendments are sufficient to overcome the 35 USC § 102, anticipation rejection of claims 1-3, 5-7, 9, 10, 13, 14, 16 and 17 by Andrási et al., U.S. Patent Numbers 5,639,751; 5,459,137; 5,521,174; 5,519,019; 5,604,223; and 5,536,832 of the last office action, which is hereby **withdrawn**.
3. The applicant's amendments are sufficient to overcome the 35 USC § 103, obviousness rejection of claims 1, 5-9 and 13-17 by Hamori et al., WO 96/04283 (U.S. equivalent 5,756,495) of the last office action, which is hereby **withdrawn**.
4. The applicant's amendments are sufficient to overcome the 35 USC § 103, obviousness rejection of claims 1-3, 5-7, 9, 10, 13, 14, 16 and 17 by Andrási et al., U.S. Patent Numbers

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5,639,751; 5,459,137; 5,521,174; 5,519,019; 5,604,223; and 5,536,832 of the last office action, which is hereby **withdrawn**.

5. The applicants' amendments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled a), f), i) and j). However, with regards to the 35 U.S.C. § 112, second paragraph rejection labeled b), c), d), e), g) and h) of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

It was stated that the applicants canceled claims 2-7 and 10-15. However, this is not so.

Claims 3, 6, 11 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

In view of the amendment dated January 10, 2003, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 8, 9, 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey

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to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

- a) The amendment to the structure of formula (I) is not described in the specification for the genus. Formula (I) in the specification contains a double bond between the nitrogen and the carbon which is bonded to the 4-aminophenyl.
- b) The amendment to the definition of R² and R³ where R² and R³ includes the moiety C₁₋₄ alkoxy is not described in the specification for the genus when X and Y together form a double bond.
- c) The amendment to the definition of R² and R³ where R² and R³ is a C₁₋₄ alkyl optionally substituted with a 5 to 6 membered saturated heterocyclic ring which contains one nitrogen and one oxygen atom and **may optionally have an oxo group su[b]stituent** is not described in the specification for the genus.

Applicant is required to cancel the new matter in the reply to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-14 and 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

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- a) Claims 1, 8, 9, 16 and 17 are vague and indefinite in that it is not known what is meant by the definition of R where R is a monovalent moiety and the definition of R is to a divalent moiety, i.e. $-(CH_2)_n-R^1-$.
- b) Claims 1, 8, 9 and 16 are vague and indefinite in that it is not known what is meant by a "sutstituent" in the definition of R^2 and R^3 .
- c) Claims 2-7 and 10-14 recite various variables and definitions which are not defined in the claim from which they depend. There is insufficient antecedent basis for this limitation in these claims.
- d) Claim 8 recites the limitation $-(CH_2)_n-CO-(CH_2)_m-R$ in the definition of R^1 . There is insufficient antecedent basis for this limitation in the claim. See process a), b) and c).
- e) Claim 8 recites the limitation "pyridyl" in the definition of R. There is insufficient antecedent basis for this limitation in the claim. See process a).
- f) Claim 8 recites the limitation "0, 1 or 2" in the definition of m. There is insufficient antecedent basis for this limitation in the claim. See process a), b) and c).
- g) Claim 8 recites the limitation "nitro" in the definition of R^2 . There is insufficient antecedent basis for this limitation in the claim. See process a), b), c), d), e) and line 5 on page 8 of the amendment.

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- h) Claim 8 recites the limitation "A and B" in the definitions for formula (I). There is insufficient antecedent basis for this limitation in the claim. See process a), b), c), d) and e).
- i) Claim 8 recites the limitation "a double bond" in the structure of formula (III) and (IV). There is insufficient antecedent basis for this limitation in the claim. See process a), b) and c).
- j) Claim 8 recites the limitation "NO₂" in the structure of formula III. There is insufficient antecedent basis for this limitation in the claim. See process a) and b).
- k) Claim 8 is vague and indefinite in that it is not known what is meant by the two different definitions for the variable Y. See process a), b) and d)
- l) Claim 8 recites the limitation "imidazolyl" in the definition of R. There is insufficient antecedent basis for this limitation in the claim. See process b).
- m) Claim 8 recites the limitation "NR³R⁴" in the definition of R. There is insufficient antecedent basis for this limitation in the claim. See process c).
- n) Claim 8 is vague and indefinite in that it is not known what is meant by the definition of R⁴ and m which are said to be defined in claim 1. See process c).
- o) Claim 8 is vague and indefinite in that it is not known what is meant by the two different definition for the variable X.
- p) Claim 8 recites the limitation "-CO-(CH₂)_p-R⁶" in the definition of R¹. There is insufficient antecedent basis for this limitation in the claim. See process d) and e).

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- q) Claim 8 recites the limitation "phenoxy" in the definition of R⁶. There is insufficient antecedent basis for this limitation in the claim. See process d).
- r) Claim 8 recites the limitation "0, 1 or 2" in the definition of p. There is insufficient antecedent basis for this limitation in the claim. See process d).
- s) Claim 8 is vague and indefinite in that it is not known what is meant by the definition of R⁷, R⁸ and p which are said to be defined in claim 1. See process e).
- t) Claim 8 is vague and indefinite in that it is not known what is meant by the definition of A and B which are said to be defined in claim 1. See lines 5 and 9 on page 8 of the amendment.
- u) Claim 18 is vague and indefinite in that it is not known what is meant by "/" in the nomenclature of the species.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-14 and 16-18 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility. The invention as claimed herein where the structure of formula (I) is totally saturated is not described in the

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specification and thus there is no statement of utility for the compounds where the bond between the nitrogen atom and the carbon which is substituted by a 4-aminophenyl is a single bond.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays and Tuesdays from 9:00 AM to 3:00 PM and from 5:30 PM to 7:30 PM and on Wednesday thru Friday from 9:00 AM to 6:00 PM.

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The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brenda Coleman
Brenda Coleman
Primary Examiner AU 1624
March 23, 2003